

**Cooperative Agreement  
Between Washington State University  
and Washington State Department of Social and Health Services**

Washington State University (WSU) and Washington State Department of Social and Health Services (DSHS) are entering into this Agreement to avoid duplication of effort with regard to institutional review board (IRB) reviews of human research protocols to be conducted by WSU faculty, students or staff in DSHS jurisdiction.

The Washington State Institutional Review Board (WSIRB) is responsible for reviewing all research studies conducted in the jurisdiction of DSHS. The WSIRB operates under Office for Human Research Protection (OHRP) Registration Numbers IRB00000093 and IRB00000094 and Federalwide Assurance Number FWA00000326.

WSU Institutional Review Board (WSU IRB) is responsible for review of all research conducted by faculty, students and staff at WSU. The WSU IRB operates under OHRP registration number IRB00000449 and Federalwide Assurance Number 00002946.

This Agreement is intended to allow faculty, students and staff of WSU to submit human research studies that will be subject to this Agreement to the WSIRB for initial and continuing review. Research that is subject to this Agreement is described in Exhibit A (attached).

Both parties agree to the following:

- A. WSU will initiate the human research protocols submitted by faculty, students, and staff of WSU to be reviewed and approved by the WSIRB. WSU researchers proposing to do human subjects research subject to this Agreement will be required to submit one human subjects application (on WSIRB application forms) to the WSU IRB Coordinator. The WSU IRB Coordinator will electronically forward the application to the WSIRB.
- B. The WSIRB agrees to conduct initial and continuing review of human research protocols subject to this Agreement on behalf of WSU in accordance with the U.S. Department of Health and Human Services OHRP regulations for the protection of human subjects as set forth in 45 CFR, Part 46, and the Food and Drug Administration regulation as set forth in 21 CFR Parts 50 and 56, and all applicable requirements of federal, state, and local laws and regulations governing the protection of human subjects. The WSIRB has established Policies and Procedures that must be followed.
- C. WSU agrees to accept the initial and continuing review by WSIRB of human research protocols conducted by WSU faculty, staff and students that are subject to this Agreement. The WSIRB will notify WSU and any affected investigator(s) in writing of its decision to approve or disapprove any protocol, or of modifications required securing IRB approval of the protocol. In the event of WSIRB disapproval of a protocol, it shall include in its written notification a statement of the reasons for its decision and shall give the investigator an opportunity to respond either in person or in writing as stated in Policies and Procedures of the WSIRB. The WSU President (or other WSU official designated by the President) reserves the right to terminate or reject a WSU researcher's protocol even when it has been approved by WSIRB.

- D. The WSIRB will prepare and maintain adequate documentation of its activities in accordance with 45 CFR 46 and 21 CFR 56, as amended. The WSIRB will provide WSU with copies of the minutes at which any action was taken regarding a WSU protocol. The WSU IRB will maintain a duplicate complete file of all activities for the protocol.
- E. The WSIRB will report to WSU and make copies of all related documents available if any one of the following occurs in WSU research or a WSU protocol:
1. Any serious or continuing noncompliance with requirements by investigators discovered by the WSIRB;
  2. Any suspension or termination of WSIRB approval of a protocol including a statement of the IRB's reasons for such action;
  3. Any violation of state or federal law that impacts a protocol or the research subjects, or
  4. Any unreasonable risk to the health, safety or confidentiality of a research subject.
- F. The WSIRB requires that all investigators, sub-investigators, and key personnel must complete and submit documentation of on-line human subjects research training. Documentation of other human subjects research training (such as the WSU IRB human subjects training presented either in person or on-line) may be accepted in place of the on-line training.
- G. The WSIRB will waive review fees for any human research protocols submitted by WSU faculty, staff or students regardless of funding source.
- H. The parties agree that this Agreement's reduction of redundancy is good and sufficient consideration for the duties this Agreement imposes on the parties.
- I. Exceptions: Any protocols submitted by WSU faculty, staff or students conducted on tribal lands or which target Native Americans as the principle study population will require review by the WSU IRB as well as the WSIRB.
- J. The WSIRB attests that the composition of the WSIRB is such as to adequately protect the rights and welfare of human research subjects enrolled in the WSU human research protocols. The WSIRB will provide WSU with an updated membership list as it changes.
- K. The WSIRB will refer any studies conducted by WSU faculty, staff or students subject to this Agreement that qualify for exemption under 45 CFR 46.101b, to the WSU IRB for administrative review and certification of exempt status.
- L. Each party to this Agreement shall be responsible only for its own acts and omissions and those of its own officers, employees, and agents. The employees or agents of each party who are engaged in the performance of this Agreement shall continue to be employees or agents of that party and shall not be considered for any purpose to be employees or agents of the other party.
- M. If a dispute arises under this Agreement, the parties agree to resolve the dispute with a Dispute Board (Board). The Board shall be chosen in the following manner:

WSU and WSIRB will each appoint one member to the Board. The members so appointed will jointly appoint an additional member to the Board. The Board will review the facts, Agreement terms and applicable statutes and rules and make a determination of the dispute. The determination of the Board shall be final and binding.

- N. This Agreement is governed by the laws of the state of Washington and any applicable federal laws. This Agreement is to be construed to conform to those laws. The parties agree that any legal action arising from this Agreement will be initiated in Spokane County Superior Court.
- O. The work to be provided under this Agreement is not assignable or delegable by either party in whole or in part, without the express prior written consent of the other party.
- P. This Agreement will remain in effect for a period of three years, beginning on the effective date of this Agreement, unless sooner terminated as provided. This Agreement will be automatically renewed and extended for successive three year periods on the same terms and conditions, unless either party notifies the other of its intent not to renew at least ninety (90) days prior to the expiration of the current term.

### **RECORDS MAINTENANCE**

The IRB shall maintain records, documents and other evidence which sufficiently and properly reflect the initial review of a protocol, all monitoring, modifications and renewals of a protocol. These records shall be available to and subject to inspection, review or audit by personnel of the parties, other personnel duly authorized by either party, the Office of the State Auditor, and federal officials so authorized by law. All books, records, documents, and other material relevant to this Agreement will be retained for three years after the expiration of the final renewal of the protocol (retention period).

### **AUTHORITY**

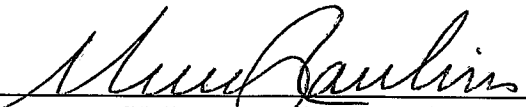
The DSHS IRB is an independent contractor. The WSIRB and its individual members are not employees, agents or legal representatives of WSU and shall not have or purport to have any right, power or authority to create any obligation or responsibility on behalf of WSU.

The Agreement may be terminated by either party at any time without cause upon ninety (90) days prior written notice.

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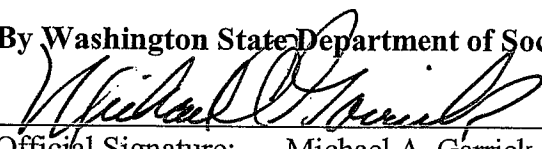
A fully executed copy of this Agreement will be retained by WSU and the WSIRB and will be made accessible to the U.S. Department of Health and Human Services OHRP.

**By Washington State University:**

  
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Official Signature: V. Lane Rawlins, President

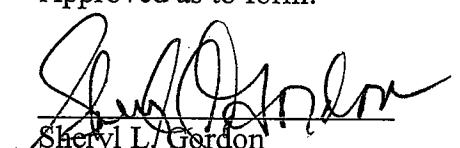
8/15/06  
\_\_\_\_\_  
Date

**By Washington State Department of Social and Health Services:**

  
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Official Signature: Michael A. Garrick,  
Human Protections Administrator

8/28/06  
\_\_\_\_\_  
Date

Approved as to form:

  
\_\_\_\_\_  
Sheryl L. Gordon  
Assistant Attorney General

Dated: 8/10/06  
\_\_\_\_\_

EXHIBIT A  
IRB Authorization Agreement

**Institution Providing IRB Review:** Washington State Department of Social and Health Services (DSHS)

IRB Registration: IRB00000093; IRB00000094  
FWA00000326

Federalwide

Assurance:

**Institution Relying on the Designated IRB:** Washington State University

IRB Registration: IRB00000449

Federalwide Assurance: FWA00002946

The parties agree that the Washington State University may rely on the Department of Social and Health Services IRB (Washington State Institutional Review Board, or WSIRB) for review and continuing oversight of its human subject research described below:

- Research conducted by Washington State University faculty, staff, and/or students in which human subjects will be identified or contacted for study recruitment through non-public record information maintained by the Washington State Department of Social and Health Services, Department of Health, and/or Department of Labor and Industries.
- Research conducted by Washington State University faculty, staff, and/or students in which individuals who reside in Washington State Department of Social and Health Services hospitals, residential facilities or contracted living settings will be identified or contacted for study recruitment.
- Research conducted by Washington State University faculty, staff, and/or students in which individually identifiable personal records and/or protected health information maintained by the Washington State Department of Social and Health Services, Department of Health, and/or Department of Labor and Industries will be accessed, used or disclosed for research purposes without written consent or authorization.
- Research sponsored by the Washington State Department of Social and Health Services, Department of Health, or Department of Labor and Industries, funded either directly with state funds or with federal pass-through funds, and subcontracted to the Washington State University for the performance of the activity.

*The review and continuing oversight performed by the Washington State Institutional Review Board will meet the human subjects protection requirements of the Washington State University OHRP-approved FWA. The WSIRB will report its findings and actions, including relevant minutes of WSIRB meetings, to appropriate officials at the Washington State University upon request. The Washington State University remains responsible for ensuring compliance with the WSIRB's determinations and with the terms of its OHRP-approved Assurance. This document is kept on file at both institutions and provided to OHRP upon request.*